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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/691,844

10/23/2003

James R. Grabek

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7590

07/26/2006

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EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,844

Applicant(s)

GRABEK ET AL.

Examiner

Henry M. Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/2/2006 has been entered.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 3-6, drawn to method of cardiac ablation, classified in class 128, subclass 898.
- II. Claim 2, drawn to RF surgical device, classified in class 606, subclass 041.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case cardiac ablation may be accomplished using trocars and cannulae for chest penetration and non-catheter RF delivery devices introduces via the cannula.

Newly submitted claim 2 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: only method claims for ablating the heart have been previously submitted.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

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on the merits. Accordingly, claim 2 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

No arguments were provided by the applicant regarding the prior art rejection of the method claim.

Drawings

This application lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the multiple barbs must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3: multiple anchor barbs on a distal section are new matter. While multiple fixation means is disclosed, the location is along the lead with no specific location defined.

Claim 4: positioning a stylet halfway down the length is new matter.

Claim 5: a hypo tube of stainless steel is new matter.

Claim 6: a fully insulated catheter body is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 3, 5 and 6 are indefinite as they claim device dependency on an independent method claim. It appears these claims were intended to be dependent on claim 2, however, they would then be subject to the same restriction as claim 2 as stated above.

Claim 3 recites the limitation "the archuate length" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "the hypo tube" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the distal tip" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0120268 to Bertolero et al. in view of U.S. Patent

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6,623,480 to Kuo et al. Bertolero et al. disclose a method for ablation of cardiac tissue for treating cardiac arrhythmias including contacting a device with epicardial tissue, using a tissue contacting member on the device to secure the device to the tissue, and ablating the tissue with an ablation member on the device. In some embodiments, the method further includes additional steps such as positioning the device on the epicardial tissue, stabilizing cardiac tissue, cooling cardiac tissue, positioning the device using a positioning device, visualizing epicardial tissue with an imaging device and/or the like (paragraph 0052). The ablation is disclosed as RF (paragraph 0059) and may be a single linear array (Fig. 4). The method includes positioning an insufflation device between the epicardial tissue and a layer of pericardial tissue and introducing an insufflation medium into the insufflation device to create a space between the epicardial tissue and the pericardial tissue (paragraph 0016). Clearly the pericardium must be intact for an insufflation procedure. Bertolero et al. do not teach anchoring the end of an ablation device and conforming the electrodes of a flexible portion onto the desired area. Kuo et al. teach a catheter and a related method for the treatment of atrial flutter utilizing radio frequency energy (Col. 1, lines 11-13) using a catheter that includes a screw-in anchoring device or anchoring hook located at the distal tip of the catheter. This device includes a corkscrew tip that is used to anchor the catheter at a preselected location during deployment, which advantageously allows the operator to bend or mold the catheter as necessary to place the electrodes at the desired target location (Col. 4, lines 35-41). The anchor may be a hook (barb) located at the distal end (Col. 4, lines 36-37). The catheter is anchored in cardiac tissue and the electrodes are positioned at the desired location for ablation. Kuo et al. disclose the use of a stylet with the device which inherently stiffens the device. Bertolero et al. teaches multiple suction apertures for anchoring to cardiac tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use

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the flexible, anchorable ablation catheter as taught by Kuo et al. in the access method of Bertolero et al. to produce lesions on the epicardial heart surface. Epicardial access is known as is using RF energy to produce lesions in the treatment of atrial fibrillation. It is proper to take into consideration not only the teachings of the prior art, but also the level of ordinary skill in the art. In re Luck, 476 F.2d 650, 177 USPQ 523 (CCPA 1973). Specifically, those of ordinary skill in the art are presumed to have some knowledge of the art apart from what is expressly disclosed in the references. In re Jacoby, 309 F.2d 513, 135 USPQ 317 (CCPA 1962).

Regarding claim 5, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Regarding claim 6, it is well known that ablation electrodes must be insulated from each other and Kuo et al. provides multiple electrodes which inherently must be insulated to be functional.

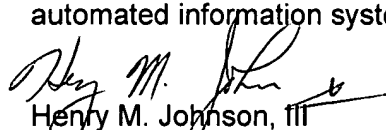
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Primary Examiner
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